



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 8 2005

iMetrikus, Inc.  
c/o Mr. Curtis M. Egan  
Chief Operations Officer  
Certified Software Solutions, Inc.  
5770 Armada Drive, Suite 100  
Carlsbad, CA 92008

Re: K042768  
MediCompass Connect  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: **February** 14,2005  
Received: February 16,2005

Dear Mr. Egan;

This letter corrects our substantially equivalent letter of February 22, 2005, regarding the incorrect year cited for the date of your submission. Please see the above date for the correction.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

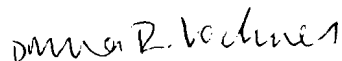
Page 2 - Mr. Curtis M. Egan


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-\_\_\_. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

1. E-mail correspondence dated March 2, 2005

## Indications for Use

510(k) Number (if known): K042768

Device Name: MediCompass Connect

### Indications for Use:

MediCompass Connect serves as an interface or a gateway between personal monitoring devices and a general purpose personal health management database. Monitoring devices that can interface to the MediCompass Connect include, but are not limited to:

- Blood glucose monitor
- Blood pressure cuffs
- Insulin pumps
- Spirometers
- Scales

MediCompass Connect is designed for professional healthcare settings and home use.

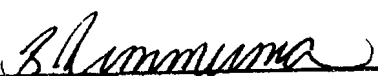
Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the-counter Use - X \_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER  
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K042768

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FEB 22 2005

## 510(k) Summary

**Date prepared:** September 29, 2004

**Submitter/Owner:** iMetrikus, Inc.  
5770 Armada Drive, Suite 100  
Carlsbad, CA 92008

**Contact person:** Dan Olivier  
16787 Bernardo Center Drive, Suite A-1  
San Diego, CA 92128

**Phone number:** (858)675-8200

**Fax number:** (858)675-8201

**Proprietary name:** MediCompass Connect

**Common name:** Data Transfer System

**Classification:** Class II. 870.1130. Noninvasive blood pressure measurement system

**Product Code:** DXN

**Substantial equivalence claimed to:**

1. K040086 – Health Buddy<sup>®</sup> with BuddyLink

**Description:**

MediCompass Connect is a system that transmits data from personal monitoring devices using standard communication methods such as telephone lines or wireless, or transmits data by using a PC that has a connection to the Internet. MediCompass Connect transmits the data from a personal monitoring devices, such as a blood pressure cuff, to a remote general-purpose personal health management database.

- Blood pressure cuffs
- Blood glucose meters
- Insulin pumps
- Spirometers
- Scales

**Comparison of technological characteristics with predicate device:**

MediCompass Connect is a system to transmit data that is substantially equivalent to the currently marketed Health Buddy® with BuddyLink (K040086). Both systems are for the communication of general purpose personal health management information.

**Devices validated for use with MediCompass Connect**

<b>Brand</b>	<b>Personal Monitoring Devices</b>	<b>Model</b>
Roche	Blood glucose monitor	Accu-Chek® Advantage
Bayer	Blood glucose monitor	Ascensia Elite™ XL (model number 3901G)
Abbott	Blood glucose monitor	TheraSense FreeStyle™ (A)**
LifeScan	Blood glucose monitor	One Touch® II®
LifeScan	Blood glucose monitor	One Touch® Profile®
LifeScan	Blood glucose monitor	One Touch® Ultra®
Becton, Dickinson, and Company	Blood glucose monitor	BD Logic™
Roche	Blood glucose monitor	Accu-Chek® Compact
Abbott	Blood glucose monitor	MediSense® Precision Xtra™
Abbott	Blood glucose monitor	MediSense® Precision Q-I-D®
Bayer	Blood glucose monitor	Ascensia® Breeze™
Roche	Blood glucose monitor	Accu-Chek® Complete
HDI (Home Diagnostics, Inc.)	Blood glucose monitor	Prestige IQ™
A&D Medical	Blood pressure monitor (arm cuff)	LifeSource™ UA-767PC
LifeScan	Blood glucose monitor	One Touch® SureStep®
Omron Healthcare	Blood pressure monitor (arm cuff)	HEM 705CP
Omron Healthcare	Blood pressure monitor (wrist cuff)	HEM 637
Becton, Dickinson, and Company	Blood glucose monitor	BD Paradigm Link™
LifeScan	Blood glucose monitor	InDuo®
Abbott	Blood glucose monitor	TheraSense FreeStyle™ (C)**
LifeScan	Blood glucose monitor	One Touch® Basic®
Roche	Blood glucose monitor	Accu-Chek® Active
Bayer	Blood glucose monitor	Glucometer Elite™ XL (model number 3901B)
iMetrikus	Personal respiratory monitor	AirWatch®
Roche	Insulin pump	Disetronic D-TRON™plus
HDI	Blood glucose monitor	TrueTrack Smart System™
Bayer	Blood glucose monitor	Ascensia® DEX®

\* Typically referred to as the (A) model, the serial number of this TheraSense Freestyle begins with A.

\*\* Typically referred to as the (C) model, the serial number of this TheraSense Freestyle meter begins with C.